In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 2, 2020

* * * * * * * * * * * * *	UNPUBLISHED
ALLA GOLDMAN, *	
*	No. 16-1523V
Petitioner, *	
v. *	Special Master Gowen
*	
SECRETARY OF HEALTH *	Ruling on Entitlement; Influenza
AND HUMAN SERVICES, *	(Flu) Vaccine; Shoulder Injury
*	Related to Vaccine Administration
Respondent. *	(SIRVA).
* * * * * * * * * * * * *	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Kyle E. Pozza, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On November 6, 2016, Alla Goldman ("petitioner"), filed a petitioner for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") as a result of receiving an influenza ("flu) vaccination on October 23, 2015. Petition at Preamble. (ECF No. 1). Based on a full review of all the evidence and testimony presented at the entitlement and damages hearing held via videoconference on May 19, 2020, I find that petitioner is entitled to compensation.[3]

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[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this opinion contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the opinion will be available to anyone with access to the Internet.** Before the opinion is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] Pursuant to §300aa-13(a)(1), in order to reach my conclusion, I considered the entire record, including all of the medical records, affidavits, and testimony submitted by both parties. This opinion discusses the elements of the record I found most relevant to the present ruling on entitlement as well as a forthcoming ruling on damages, which will fully incorporate the same factual summary.

I. Procedural History

Petitioner (by and through her original counsel at Muller Brazil LLP) filed the petition accompanied by Petitioner's Exhibits (Pet. Exs.) 1-6. The claim was originally assigned to the Chief Special Master's Special Processing Unit (SPU) docket, which is designed to expedite to the processing of claims that have historically been resolved without extensive litigation. (ECF No. 5). On December 21, 2016, the Chief Special Master directed respondent to file a status report indicating how he intended to proceed in this case. Scheduling Order (ECF No. 8).

On March 21, 2017, respondent advised that he was willing to engage in discussions regarding a reasonable settlement of petitioner's claim. Respondent's (Resp.) Status Report (ECF No. 10). On April 21, 2017, petitioner advised that she had conveyed a settlement demand. Pet. Status Report (ECF No. 13). Petitioner also filed additional records. Pet. Exs. 7-9. Then on July 24, 2017, petitioner then advised that the parties had explored settlement but were unable to reach an agreement. Pet. Status Report (ECF No. 20). On August 2, 2017, the SPU staff attorney held a status conference at the parties' request to discuss further proceedings. Scheduling Order (ECF No. 21). Subsequently on August 22, 2017, the parties advised that they had discussed mediation and did not believe it would be beneficial in this case. Joint Status Report (ECF No. 22).

On October 10, 2017, respondent filed his report pursuant to Vaccine Rule 4(c) (Resp. Rep't) (ECF No. 23). Respondent averred that pages appeared to be missing from the records of a July 11, 2016 appointment with a pain management specialist, Dr. Ramundo. Petitioner was requested to obtain these records. *Id.* at n. 1 (referencing Pet. Ex. 5. Respondent averred that the case was not appropriate for entitlement under the terms of the Vaccine Act. Respondent first noted that it appeared that petitioner was claiming a SIRVA claim, but the petition was filed prior to the addition of SIRVA as an injury on the Table. *Id.* at n. 2, citing 42 C.F.R. § 100.3(e)(1); Fed. Reg. 11321 (Fed. 22, 2017). Respondent averred that even if the amended Table did apply to this petition, it would not meet the Table criteria, because (1) the contemporaneous medical records do not support onset within 48 hours after the vaccination and (2) there is electrodiagnostic evidence that petitioner suffers a left-sided C8 radiculopathy which would prohibit a finding that petitioner suffered a Table SIRVA injury. *Id.* at n. 2.

On October 11, 2017, petitioner filed a statement from the treating physician Dr. Ramundo in support of vaccine causation. Pet. Ex. 10. On October 13, 2017, the Chief Special Master reassigned the claim to my docket. Order (ECF No. 26). On October 23, 2017, I held an initial status conference with counsel. Scheduling Order (ECF No. 27).

On November 8, 2017, petitioner filed notice that she had transferred her representation in this claim from Muller Brazil, LLP to attorney Richard Gage. Pet. Mot. (ECF No. 29).

On December 20, 2017, I held another status conference, then directed petitioner to file updated records and explore the prospects for settlement. Petitioner also requested that I reserve hearing dates in May 2020. The parties agreed that if the case did proceed to a hearing, it should address both entitlement and damages. Scheduling Order (ECF No. 30).

On March 19, 2018, petitioner filed an amended petition expressly alleging a shoulder injury related to vaccine administration (SIRVA) beginning within 48 hours of the influenza vaccine, as listed on the Vaccine Injury Table. Amended Petition (ECF No. 34). Petitioner filed additional records as Pet. Exs. 9-11.[4]

On June 8, 2018, the parties advised that the record appeared to be complete and that petitioner would convey a demand to respondent within 30 days. Joint Status Report (ECF No. 41). On July 6, 2018, respondent advised that tentative settlement was discussed with petitioner's prior counsel, but not with current counsel. Resp. Status Report (ECF No. 42). That same day, petitioner advised that respondent's prior offer was inadequate for petitioner's injury and that further settlement negotiations would not be successful. Petitioner's counsel wished to retain a life care planner and proceed to the hearing which was scheduled for May 14-15, 2020. Pet. Status Report (ECF No. 43). On August 2, 2018, I convened a status conference during which the parties confirmed their positions. Petitioner advised that he wished to retain a life care planner closer in time to the scheduled hearing, with which plan the respondent agreed. I advised that absent other developments, I intended to revisit the case in approximately June 2019. Scheduling Order (ECF No. 44). Afterwards, respondent's counsel changed from Lynn Ricciardella to Heather Pearlman (ECF No. 45), then to Kyle M. Pozza. (ECF No. 46).

On July 1, 2019, I convened a status conference to revisit the case. Petitioner was ordered to file outstanding records, specifically of the MRI of the cervical spine in June or July 2016 and the missing pages from the July 11, 2016 appointment with Dr. Ramundo (previously requested in respondent's Rule 4(c) report). Petitioner was also directed to file affidavits addressing the onset of her shoulder injury and updated medical records. I allowed the parties to retain life care planners, but also encouraged continued efforts towards informal resolution. Scheduling (ECF No. 47).

On August 2, 2019, petitioner filed the missing medical records. Pet. Exs. 12-14. She also filed supplemental affidavits from herself, her husband Walter Goldman, and her daughter Rachel Goldman. Pet. Exs. 15-17. She also filed documentation of out-of-pocket costs. Pet. Ex. 18. Petitioner also conveyed a demand and her proposed life care plan to respondent. Pet. Status Reports (ECF Nos. 51, 58). Respondent retained his own life care planner, who requested additional records. Resp. Status Reports (ECF Nos. 60, 62). Petitioner filed the additional records as Pet. Exs. 20-26.

Following a status conference on March 17, 2020, *see* Scheduling Order (ECF No. 71), the parties filed their proposed life care plans. Pet. Ex. 27; Resp. Ex. A.

[4] These somewhat overlap with prior filings. Mr. Gage's Pet. Ex. 9 (ECF No. 36-1) appears to be duplicative of Muller Brazil's Pet. Ex. 6 (ECF No. 1-9): Institute of Neurology and Neurosurgery of St. Barnabas records pertaining to an EMG/NCS study on August 16, 2016.

Mr. Gage's Pet. Ex. 10 (ECF No. 36-2) contains some new records and some duplicates of records filed as Muller Brazil's Pet. Ex. 8 (ECF No. 18-1). Both are records from petitioner's pain management physician Dr. Ramundo.

During another status conference on April 30, 2020, the parties confirmed that they continued to discuss informal resolution, but petitioner felt that they remained too far apart on pain and suffering. I provided my tentative views regarding a reasonable life care plan. Scheduling Order (ECF No. 77, attaching Ct. Ex. 1 – Resp. Life Care Plan Annotated). Afterwards, the parties filed additional information regarding equipment costs to be included in the life care plan. Pet. Ex. 28; Resp. Ex. C. Petitioner also filed Dr. Ramundo's curriculum vitae (CV) as Pet. Ex. 29.

A hearing on both entitlement and damages was held via videoconference on May 19, 2020.[5] The witnesses were petitioner, her husband Mr. Walter Goldman, and her treating physician Dr. Ramundo. Respondent did not present any witnesses. *See* Transcript (Tr.) (ECF No. 85). Petitioner filed a post-hearing brief on May 26, 2020 (ECF No. 82), to which respondent responded on June 26, 2020 (ECF No. 87), and petitioner replied on July 13, 2020 (ECF No. 88). Accordingly, the matter is ripe for a ruling on entitlement.

II. Factual Record

A. Medical Records

1. Pre-Vaccination

Petitioner was born in 1959. Pet. Ex. 1 at 2. She resided in New Jersey with her husband and daughter. She was employed as a marketing director for the Jordache Jeans brand until approximately December 1999. *See* Tr. 73, 85; Pet. Ex. 23 at 10, 159.

Petitioner was determined to be disabled under the Social Security Administration's rules as of November 30, 1999 and entitled to Social Security Disability (SSD) benefits beginning in May 2000. Pet. Ex. 25 at 1. The supporting medical records and paperwork reflects a working diagnosis of chronic fatigue syndrome. *See, e.g.* Pet. Ex. 23 at 60, 64, 118, 119, 128, 159, 160, 162, 181, 184, 187, 189, 222, 223. Many other complaints are mentioned including fibromyalgia with trigger points, headaches, and insomnia. The SSD file details how petitioner's chronic fatigue syndrome and other complaints affected her life. In August 2000, petitioner completed an "Activities of Daily Living (ADL) Questionnaire". She wrote that on a typical day, she would get up very late. She would read or watch television but had trouble concentrating. She would go out of the house to get some air. In the afternoon she would just rest or go to her doctor. Then she would have dinner and go to bed. Pet. Ex. 23 at 19. Petitioner wrote that her husband did the shopping and most of the house cleaning. *Id.* at 19-20. Occasionally they hired help for the household maintenance. *Id.* at 20. Petitioner could not manage their money because of her difficulties with concentration and memory. *Id.* She was too sick to cook so she ate prepared meals. *Id.* She could drive only short distances without getting dizzy and fatigued. *Id.* Her husband drove most of the time and for longer distances. *Id.* However, petitioner was able to groom herself (e.g., washing, bathing, dressing, shaving). *Id.* at 23. Additionally, the SSD file

[5] Due to the COVID-19 pandemic, the hearing was held via videoconference with participants located in Washington, District of Columbia; Annapolis, Maryland; Cheyenne, Wyoming; and two locations in northern New Jersey.

does not reflect any pain, limitations in range of motion, or other complaints specific to petitioner's left shoulder. The SSD file covers approximately 1999 – 2002.

There are no further medical records from 2002 until October 2012, which marks three years prior to the vaccination at issue. The records from October 2012 and onward reflect that petitioner had the same chronic conditions that were detailed in her original SSD file and she continued to have regular appointments with her longtime primary care provider, Dr. Leon Smith. For example, at a June 23, 2015 appointment, petitioner was recorded to have a history of severe fatigue, right leg pain, labyrinthitis, trigger points, fibromyalgia, and insomnia. Pet. Ex. 2 at 88. She reported some relief of muscle pain with L-carnitine. *Id.* She had no change in muscle weakness or fatigue. *Id.* Despite the muscle weakness, she had "no limitation in range of motion, no paresthesias or numbness, no swelling." *Id.* Dr. Smith's impression was chronic fatigue syndrome and possible apnea for which petitioner refused a sleep test. *Id.* at 89.

On October 20, 2015 (three days prior to the vaccination), petitioner returned to Dr. Smith complaining of fatigue associated with muscle pain and weakness. Pet. Ex. 2 at 81-83. On review of the musculoskeletal system, petitioner "report[ed] myalgias" (without specifying any particular part of the body). However, Dr. Smith recorded that she had "no joint pain. No limitation of range of motion, no paresthesias or numbness, no swelling." *Id.* at 82. Dr. Smith's assessment was orthostatic hypertension, dizziness, and myalgia, and fibromyalgia. *Id.* at 83.

2. Post-Vaccination

On October 23, 2015, petitioner received an intramuscular flu vaccination at Walgreens Pharmacy. Pet. Ex. 1 at 2. While not indicated in the Walgreens record, the later records and testimony provide preponderant evidence that petitioner is right-hand dominant and that she received the vaccine in the left arm. *See, e.g.*, Pet. Ex. 2 at 75; Pet. Ex. 3 at 21; Tr. 56-57, 95.

The first record of medical care following the flu vaccine is from January 12, 2016, when petitioner returned to Dr. Smith. He recorded that petitioner "present[ed] with left arm pain after receiving influenza vaccine. Associated symptoms include limited ROM. Denies swelling, erythema. [Petitioner] reports she has difficulty carrying out daily tasks including getting dressed, putting on a seatbelt, driving the car. Reports no relief with Tylenol." Pet. Ex. 2 at 75. On review of the musculoskeletal system, petitioner reported arm pain. *Id.* Dr. Smith recorded on examination: "Tenderness, limited ROM to left upper arm". *Id.* Dr. Smith's assessment was left shoulder bursitis. He advised that petitioner manage her pain by applying heat and also taking non-steroidal anti-inflammatory medication (NSAIDs), namely the over-the-counter medication Aleve and the prescription medication Mobic (meloxicam). He also referred petitioner to physical therapy. *Id.* at 75-76.

Dr. Smith also ordered an x-ray of the left shoulder, which was performed on February 24, 2016. The report reflects a history of pain and bursitis. The impression was unremarkable. Pet. Ex. 2 at 77.

On March 7, 2016, petitioner began treatment for her left shoulder at JAG Physical Therapy. The history provides: "Patient's shoulder pain began in OCT 2015, after she received a flu shot in the left shoulder. Her ROM became limited in January 2016 when she followed up with her PCP who prescribed meloxicam and PT." Pet. Ex. 4 at 91. Petitioner reported consistent dully/achy pain in her left shoulder that became sharp with movement; difficulty with all functional reaching activities which impeded her self-care and ADLs, and that the pain and discomfort interrupted her sleep pattern. *Id.* Petitioner rated her pain to be currently and at best six out of ten; at worst it was eight out of ten. *Id.* On physical examination, petitioner could actively bring the left shoulder on flexion to 70 degrees, abduction to 45 degrees, reach on external rotation to her ear, and reach on internal rotation to her sacrum. *Id.* at 92. Petitioner had difficulty lifting her arm against gravity due to pain. *Id.* Passive range of motion achieved flexion to 110 degrees; abduction to 100 degrees, and external rotation in neutral position to 45 degrees. *Id.* These passive measures were also associated with pain. *Id.* Her left shoulder muscle strength in all measures (flexion, abduction, internal rotation, and external rotation) were all 3/5 compared to the right shoulder at 5/5. *Id.* Petitioner was also recorded to have "postural dysfunctions and poor scapular stabilizers that affect biomechanics at shoulder with movements." *Id.* The physical therapist's assessment was that petitioner's primary functional limitation was carrying, moving, and handling objects. *Id.* at 93. She was at least sixty per cent (60%) but less than eighty per cent (80%) impaired in this function. *Id.* Her rehabilitation potential was "good" with skilled physical therapy. *Id.*

On March 29, 2016, Dr. Smith recorded that petitioner had persisting left shoulder pain with some relief from NSAIDs and physical therapy. Dr. Smith maintained the diagnosis of bursitis. Pet. Ex. 2 at 61-63.

Dr. Smith also ordered an MRI of the left shoulder which took place the following day, March 30, 2016. The original report provides: "History: 2 months of shoulder pain and limited range of motion." Pet. Ex. 3 at 23. On April 5, 2016, the same radiologist noted "an error in the clinical history of this patient. The clinical history should read: "History: Shoulder pain and limited range of motion since the end of October." *Id.* at 22-24. The findings were suggestive of adhesive capsulitis and mild glenohumeral joint osteoarthritis. *Id.* at 23.

On April 12, 2016, Dr. Smith recorded petitioner's repeated history of left shoulder pain after receiving flu vaccine. Pet. Ex. 2 at 56. She had been attending physical therapy but had missed the last two weeks due to cold symptoms. *Id.* Consistent with the shoulder MRI report, Dr. Smith's impression was left shoulder adhesive capsulitis. *Id.* at 57, 58. Dr. Smith planned continued physical therapy, NSAIDs, and a referral to an orthopedist. *Id.* at 57.

Petitioner had attended regular physical therapy sessions three times a week through to March 30, 2016. Pet. Ex. 4 at 67. She then missed nearly a month of physical therapy due to a "severe case of the flu." She resumed physical therapy on April 25, 2016. *Id.* at 66. On May 18, 2016, she was discharged from physical therapy due to reaching the Medicare reimbursement cap for physical therapy sessions and being unable to choose the self-pay option. *Id.* at 50.

On June 1, 2016, petitioner (on referral from Dr. Smith) presented as a new patient to Columbia University Medical Center, Orthopedics Center. Petitioner completed a new patient intake form on which she endorsed a history of chronic fatigue syndrome. Pet. Ex. 3 at 19. On review of systems, petitioner endorsed numerous symptoms within the past six to twelve (6 – 12) months including headache. *Id.* at 20. The specific reason for the visit was "Shoulder pain/ injury (left)". *Id.* at 19. Petitioner provided additional information about the left shoulder injury including that it occurred "following flu shot on Oct. 23, 2015". *Id.* at 21, 22. The pain was associated with "limited range of motion." *Id.* at 21, 22. It was also associated with "neck pain, headache." *Id.* at 22. During this appointment, the orthopedist, Dr. Christopher Ahmad, recorded: "She has had many months of left shoulder pain, onset in early October." Pet. Ex. 3 at 15. Three months later, Dr. Ahmad amended his record to note that the intake form reflected onset of left shoulder pain following a flu shot on October 23, 2015. *Id.* At this June 1, 2016, appointment, Dr. Ahmad conducted a physical exam and recorded an impression of: "Left shoulder glenohumeral joint arthritis and rotator cuff tendinosis." *Id.* Dr. Ahmad discussed treatment options. Petitioner declined a cortisone injection. *Id.* Accordingly, Dr. Ahmad recommended NSAIDs and further physical therapy. *Id.*

On June 8, 2016, petitioner completed a patient health questionnaire for purposes of resuming treatment at JAG Physical Therapy, including the following fields:

1. Describe your symptoms: Left shoulder/ upper arm, neck pain, headaches.
a. When did your symptoms start?: Following the flu shot of 10/23/2015.
b. How did your symptoms begin?: With severe shoulder pain.

Pet. Ex. 4 at 6. Petitioner also endorsed having a history of headaches. *Id.* at 7.

At the June 13, 2016 physical therapy re-examination, petitioner reported that since stopping therapy a month prior, her left shoulder condition had regressed. She was moderately impaired in all ADLs and self-care activities such as brushing and washing her hair, washing her back, overhead reaching, lifting, carrying, and pushing objects. Pet. Ex. 7 at 61. Petitioner also reported that her pain remained at best six out of ten and at worst eight out of ten. *Id.* However, compared to the initial evaluation in March 2016, the objective findings were slightly improved. Petitioner could achieve active flexion to 85 degrees and active abduction to 90 degrees, albeit with pain. *Id.* at 62. She was between forty per cent (40%) and sixty per cent (60%) impaired. *Id.* Her rehabilitation potential with skilled therapy remained "good". *Id.* This appointment marked the resumption of regular physical therapy sessions approximately three times per week, as before.

The primary care provider Dr. Smith referred petitioner to Giovanni Ramundo, M.D.[6] Dr. Ramundo continued to treat petitioner over the subsequent years; wrote a September 2017

[6] With regard to qualifications, Dr. Ramundo graduated from Lafayette College with a bachelors' degree in Biology, with honors, in 1986. Pet. Ex. 29 at 2. He obtained a medical degree from Penn State University – the Milton S. Hershey Medical Center in 1990. *Id.* He then served as an internal medicine intern from 1990 – 1991; an anesthesiology resident from 1991 – 1993; and an anesthesiology chief resident from 1993 – 1994. *Id.* Dr. Ramundo worked at a clinical anesthesiology practice in Florida from 1994 – 1996. *Id.* Afterwards, he returned to Hershey Medical Center where he served as a pain medicine fellow and clinical instructor from 1996 – 1997. *Id.* In 1997, Dr. Ramundo began practicing pain medicine in the state of New Jersey. *Id.* He opened his current practice,

"narrative report" supporting that the October 2015 flu vaccination caused her left shoulder pain and limited range of motion (with sequelae of left arm weakness, pain radiating into the neck, and headaches); and testified at the 2020 hearing on entitlement and damages. The following section relies primarily on his contemporaneous medical records, with additional detail from his narrative report and his testimony at the May 2020 hearing.

At the June 27, 2016 initial consult, Dr. Ramundo recorded that petitioner had a history of chronic fatigue syndrome. Pet. Ex. 5 at 14. But at that visit, her chief complaint was "left shoulder pain that radiates into her neck. Her pain was associated with headaches. She has also noticed she has weakness in the left arm compared to the right. Pain started about 8 months ago, after a flu shot, before the flu shot she never had this pain." *Id.* Dr. Ramundo observed limited range of motion on examination and his initial impression was cervicalgia. *Id.* at 17.

At the hearing, Dr. Ramundo opined that the neck and shoulder are closely related. Pain originating in the shoulder can radiate to the neck; conversely, pain originating in the neck can radiate to the shoulder. Both scenarios can be confusing. The key with any pain condition is to make the right diagnosis. Accordingly, Dr. Ramundo will painstakingly rule out any other pathology as the course of pain. Tr. 8-10.

In petitioner's case, Dr. Ramundo first ordered an MRI of the cervical spine, *see* Pet. Ex. 5 at 17, which occurred on June 28, 2016, Pet. Ex. 12 at 1. The original report provides: "One-month history of neck and left shoulder pain." *Id.* Approximately two weeks later, the same radiologist entered an addendum providing that was an error and the history should read: "One-month history of neck pain AND LEFT SHOULDER PAIN SINCE 2015." *Id.* at 2. Of note, there was "no evidence for disc herniation, central stenosis, or neural foraminal stenosis" at C7-T1. *Id.* The impression was: "Mild degenerative changes of the cervical spine with mild right-sided foraminal narrowing at C4-5 and no lateralizing findings on the left. Tiny left-sided thyroid nodule." *Id.*

On July 11, 2016, petitioner returned to Dr. Ramundo who reviewed the MRI report, then ordered an EMG "to determine where her left arm pain is coming from." Pet. Ex. 19 at 3. He also recommended additional physical therapy and unspecified injections. *Id.* He recorded that petitioner "prefer[red] to avoid surgery if possible." *Id.*

On August 5, 2016, petitioner was again discharged from physical therapy due to reaching the Medicare reimbursement cap. She was instructed to follow a home exercise program until she was recertified. Pet. Ex. 7 at 33-34.

At a follow-up appointment on August 16, 2016, Dr. Smith recorded that petitioner was "refusing the surgical option for her frozen shoulder". Pet. Ex. 2 at 3.

Pain Medicine Physicians LLC in Millburn, New Jersey, in 2012. *Id.* His board certifications include pain medicine, EMG testing, and anesthesiology. *Id.* Dr. Ramundo testified that his current practice is "probably 90 percent pain, 10 percent anesthesia." Tr. 7.

On August 23, 2016, Dr. Ramundo recorded that petitioner continued to have pain in her left shoulder, pain radiating into her neck, headache, and weakness in the left arm compared to the right. Pet. Ex. 5 at 7. Petitioner rated her current pain at three or four out of ten. *Id.* This pain interfered with her sleep. *Id.* Dr. Ramundo reviewed an EMG/NCS which showed "electrodiagnostic evidence for chronic and ongoing mild left C8 radiculopathy [and] a mild left median neuropathy at the wrist as seen in carpal tunnel syndrome", without evidence for a left ulnar neuropathy or left brachial plexopathy. *See* Pet. Ex. 6. However, Dr. Ramundo recorded: "Her pain is not in a C8 pattern". Pet. Ex. 5 at 11. He noted the temporal association with the flu vaccine. *Id.* His assessment was bursitis and frozen shoulder (also known as adhesive capsulitis). *Id.* at 7-8. He recorded: "She is not interested in any injections at this time because she feels her pain problem is from the vaccine injection and does not want any more injections." Pet. Ex. 5 at 7-11; *see also* Pet. Ex. 10 at 2; Tr. 12-14.

On September 7, 2016, the orthopedist Dr. Ahmad saw petitioner on follow-up. He conducted a physical exam. He reviewed the EMG report with an impression of chronic, mild left C8 radiculopathy and mild left median neuropathy at the wrist as seen in carpal tunnel syndrome. Pet. Ex. 3 at 9. Dr. Ahmad's impression was: "left shoulder glenohumeral joint arthritis and rotator cuff tendinitis with cervical radiculopathy and mild carpal tunnel syndrome." *Id.* However, Dr. Ahmed did not seem to review the MRI of the cervical spine which did not have any significant findings that would correlate with a C8 radiculopathy. This MRI had been ordered by Dr. Ramundo and obtained on June 28, 2016, prior to the September 7, 2016 follow-up with Dr. Ahmad. Thus, Dr. Ahmad's assessment of a cervical radiculopathy was not based on all of the available information and is therefore less persuasive. Dr. Ahmad and petitioner discussed again the treatment options including arthroscopy, cortisone injection, and physical therapy. *Id.* at 10. Petitioner chose to continue with physical therapy. *Id.* The record provides that petitioner would follow up with Dr. Ahmad in four to six weeks, but there are no further records from his practice. *Id.*

After a one-month gap, on September 7, 2016, petitioner had a physical therapy recertification. She continued to complain of left shoulder pain, again rated at best six out of ten and at worst eight out of ten. However, the "frequency and duration ha[d] improved". Pet. Ex. 7 at 27. Petitioner continued to report similar restrictions to ADLs due to pain, weakness, and fatigue through the left upper extremity. *Id.* The left shoulder objective findings were again slightly improved, with active flexion to 90 degrees, active abduction to 100 degrees, and external rotation beyond the ear to the sub-cranial region. *Id.* at 28. She also had improved passive range of motion with flexion to 115 degrees, abduction to 110 degrees, external rotation to 80 degrees, and internal rotation to 20 degrees. *Id.* These measures were associated with pain. *Id.* The physical therapist recorded: "Every time patient stops PT she returns with less functional abilities and decreased ROM. Pain intensity and frequency has decreased with PT…" *Id.* at 29.

In fall 2016 with the resumption of physical therapy, petitioner had decreased pain but continued weakness in the left shoulder. On September 21, 2016, she reported: "My pain is tolerable but the weakness is what is most bothersome to me now." Pet. Ex. 7 at 23. On September 28, 2016, "the weakness is what is bothering [petitioner] most lately." *Id.* at 21. On October 5, 2016, she reported: "The pain came back a little this weekend but then went away.

The weakness is still there." *Id.* at 19. On October 19 and again on October 26, 2016, the weakness was "the most troublesome." *Id.* at 15, 17. At the next several appointments, petitioner's primary concern was neck pain. *Id.* at 9, 11, 13. On November 30, 2016, petitioner reported that within the past few weeks, her pain had improved to the point that it was "minimal during her ADLs." *Id.* at 7. She rated her pain to be at best zero out of ten, at present three out of ten, and at worst eight out of ten. *Id.* She had continued weakness which disrupted ADLs such as reaching into a cabinet, picking up heavy objects or even a jug of water, or certain self-care tasks such as washing her hair. *Id.* She reported that she was also experiencing weakness in her lower extremities for which she would follow up with a doctor. *Id.* Petitioner provided a similar report at another session on December 7, 2016, *see also id.* at 1-2, after which there is a gap in the physical therapy records.

On December 14, 2016, Dr. Ramundo recorded a similar description of petitioner's left shoulder pain and neck. She also had new pain in her mid-back and weakness in her lower extremities. Dr. Ramundo ordered an MRI of the lumbar spine and an EMG/NCS of the bilateral lower extremities. Pet. Ex. 8 at 17-20; *see also* Pet. Ex. 10 at 2; Tr. 15-16.

On January 23, 2017, Dr. Ramundo recorded that petitioner had taken a break from physical therapy "due to insurance not paying for visits and she will resume next week." Pet. Ex. 8 at 12. Dr. Ramundo recorded: "Her main concern is the weakness and tingling in lower extremities right worse than left, left arm weakness, and her low back pain. Left shoulder pain radiates into her neck and is associated with left-sided headaches. Her shoulder and back pain both interfere with her sleep. Currently she rates her left shoulder and back pain a 5/10." *Id.* Petitioner was still taking the NSAID meloxicam for her pain. *Id.* Dr. Ramundo reviewed that an MRI of the lumbar spine revealed a right L4 and L5 radiculopathy. *Id.* at 14. Dr. Ramundo planned an EMG of the lower extremities to evaluate for her weakness. *Id.* at 14; *see also* Pet. Ex. 10 at 2. Dr. Ramundo testified that at this point, physical therapy was "absolutely" beneficial for her left shoulder and that should be continued. Tr. 16-18.

On February 27, 2017, Dr. Ramundo recorded that as a result of her mother passing away, petitioner still had not resumed physical therapy. Pet. Ex. 8 at 8. She was doing only home exercises that were not providing any relief. *Id.* Dr. Ramundo recorded: "Currently she rates her left shoulder and back pain a 5/10. Her left shoulder and low back pain both interfere with her sleep… She has not had prior treatment for her low back. She currently rates her back pain at a 6-7/10." *Id.* Dr. Ramundo was still waiting for the EMG/NCS to evaluate petitioner's lower extremity weakness. *Id.* at 11. He wrote that if the weakness continued, petitioner would need to see a neurologist and possibly a spine surgeon. *Id.* However, petitioner wanted to do physical therapy and see if the weakness would resolve on its own. *Id.* Dr. Ramundo testified that he recommended also resuming physical therapy for her left shoulder because: "When she did therapy, she felt better. Her pain was diminished. Ultimately, I think it would minimize her risk of developing an adhesive capsulitis to the point where she would lose range of motion in the entire shoulder." Tr. 18. Dr. Ramundo also believed that physical therapy might help somewhat with the left arm weakness. *Id.*

On March 20, 2017, Dr, Ramundo recorded that the EMG confirmed right L4 and L5 radiculopathies. Pet. Ex. 8 at 1. In addition, petitioner had "continued left shoulder pain that seems to be getting wors[e] since she has not been undergoing PT. She states reaching is difficult and painful compared to her right shoulder." *Id.* Petitioner rated both "her left shoulder and back pain at 5/10. Her left shoulder and low back pain both interfere with her sleep." *Id.* Dr. Ramundo recorded: "The plan is to start physical therapy for her neck pain, left shoulder pain, and low back pain. Patient was getting relief from PT for her left shoulder therefore she will start it for her neck and low back." *Id.* at 4; *see also* Pet. Ex. 10 at 2; Tr. 18-19.

On April 12, 2017, petitioner was reexamined at JAG Physical Therapy for "pain in shoulder and neck with frequent occurrence of HA [headaches]", which was associated with "overhead reaching, lifting, carrying, pushing, and pulling." Pet. Ex. 9 at 4. She reported that her left shoulder pain was at best zero out of ten, at present three out of ten, and at worst eight out of ten. *Id.* Since the last physical therapy appointment several months prior, petitioner's active range of motion had improved; flexion was to 150 degrees and abduction to 100 degrees. *Id.* at 5. She had maintained external rotation to the subcranial area and internal rotation to the sacrum. *Id.* During this physical therapy examination, petitioner also reported "LE [lower extremity] weakness leading to dysfunction when getting dressed in the morning, cooking, cleaning, and performing housework… prolonged standing, bending, squatting, and walking < 1 mile". *Id.* at 4. She reported that her lower back pain was zero out of ten, at present four out of ten, and at worst four out of ten. *Id.* The physical therapist developed a plan of treatment for the left shoulder and would follow up with petitioner's doctor (presumably Dr. Ramundo) on the objective findings relating to her lower extremities. *Id.* at 7. There are no further records from JAG Physical Therapy; as discussed below, petitioner underwent additional physical therapy to Dr. Ramundo's practice Pain Medicine Physicians LLC.

On July 10, 2017, Dr. Ramundo recorded that petitioner had completed the course of physical therapy. She rated both her left shoulder pain and low back pain to be approximately 4/10. Both interfered with her sleep. Petitioner still did "not wish to have any injections or surgeries" and wanted to continue conservative treatment. Gage Pet. Ex. 10 at 9. Dr. Ramundo recommended further physical therapy. *Id.* at 12; *see also* Pet. Ex. 10 at 2; Tr. 19-21.

In August 2017, petitioner began treatment with Joseph Musso, C.C.S.P., at the Musso Chiropractic Center for a total of four complaints: 1) bilateral neck pain; 2) bilateral low back pain; 3) bilateral mid-back pain; and 4) left shoulder pain. Pet. Ex. 11 at 1. Dr. Musso recorded on physical examination of the left shoulder that flexion was to 160 degrees, extension to 40 degrees, internal rotation to 80 degrees, external rotation to 70 degrees, abduction to 140 degrees, and adduction to 25 degrees. *Id.* at 3. Most of these measures were achieved with "moderate pain". *Id.*[7]

[7] Dr. Musso's record does not state whether these measures are of active or passive range of motion. During the hearing, Dr. Ramundo reviewed this record and testified that his understanding was that Dr. Musso was measuring passive range of motion. Tr. 22.

On September 25, 2017, Dr. Ramundo wrote a narrative report. After reviewing petitioner's past medical history, work-up and treatment, he wrote:

> My impression at this time is that her chronic pain syndrome is secondary to the left flu shot. She may have been predisposed to a cervical radiculopathy and lumbar radiculopathy, but all her complaints occurred after her flu shot. The flu shot led to an adhesive capsulitis in the left shoulder and I believe this affected the mechanics of her neck. Her EMG did show a C8 radiculopathy; however, she did not have any significant pathology noted on MRI at C7-T1. She had some mild degenerative changes of the cervical spine with some right-sided foraminal narrowing at C4-5, but all her pain complaints were on the left side involving the shoulder. In my medical opinion, her chronic neck pain, shoulder pain, and headaches are secondary to the flu shot that she received because there is not enough pathology warranted on MRI to cause the type of pain syndrome that she has."

Pet. Ex. 10 at 3; *see also* Tr. 26-28.

On October 23, 2017, Dr. Ramundo recorded that petitioner rated her left shoulder pain at four out of ten. She was unable to raise her shoulder above 90 degrees due to pain. Her pain varied depending on her activity level. She was taking meloxicam when her pain was severe. Pet. Ex. 10 at 27-30.

Four months into the course of chiropractic treatment, on December 15, 2017, Dr. Musso recorded that petitioner's left shoulder flexion was to 170 degrees, extension to 45 degrees, internal rotation to 80 degrees, external rotation to 70 degrees, abduction to 160 degrees, and adduction to 30 degrees. Pet. Ex. 11 at 47. These measures were achieved with "mild pain". *Id.* The further chiropractic records – dating to May 2019 – list petitioner's complaints of and treatments for pain in the left shoulder as well as neck, mid-back and lower back. However, the further records do not include further physical examinations of the left shoulder. *See generally* Pet. Ex. 11 at 49-70; Pet. Ex. 13; Pet. Ex. 21.

On January 16, 2018, Dr. Ramundo recorded that petitioner again presented with left shoulder pain. She was having difficulty lifting overhead, putting on clothes, combing her hair, and lifting grocery bags, pots, and pans. She rated her shoulder pain with activity as nine out of ten. Pet. Ex. 10 at 39-41. Dr. Ramundo testified that a person with this level of pain would barely be able to get out of bed. Tr. 30.

Also on January 16, 2018, at the same practice of Pain Medicine Physicians LLC, petitioner began physical therapy. The "chief complaint" listed low back pain which was associated with difficulty sitting, standing for more than fifteen minutes, walking more than two blocks, lifting grocery bag, bending over and tying her shoe laces, and putting on her pants. Gage Ex. 10 at 39. The "chief complaint" also listed left shoulder pain which was associated with moving overhead, fastening a bra behind her back, putting on other clothes, doing her hair, and lifting grocery bags, pots, and pans. *Id.* The physical therapist planned a course of treatment which would address both her low back and her left shoulder issues. *Id.* at 41.

Dr. Ramundo continued to see petitioner over the next two years. His last medical record filed is from February 4, 2020, at which petitioner reported shoulder pain at four out of ten. She also had pain in her low back and her knee. She was taking several alternative medicines (milk thistle, Boswellia, turmeric root extract). Pet. Ex. 22 at 6. She also had a prescription for meloxicam, specifically 7.5 mg, 1 tablet per day. *Id.* However, petitioner took meloxicam "only when her pain was severe". *Id.* at 9.

Dr. Ramundo testified that at this point, petitioner had "chronic" and "permanent" left shoulder pain, limited range of motion, and limited activities of daily living. She will always need to "wal[k] the tight rope" between too little activity (which will further decrease her range of motion) and too much activity (which will be associated with increased pain). Tr. 40-41. Dr. Ramundo testified that physical therapy and chiropractic treatment were both helpful in maintaining the range of motion petitioner had, although that remained abnormal and she continued to have pain. Dr. Ramundo testified that at this point, petitioner's shoulder injury appeared to be chronic and not going away. Tr. 22-26, 29, 31-42.

Dr. Ramundo summarized that petitioner developed bursitis. Tr. 13. He explained that the bursa is a soft fluid sac which allows tendon to slide in the shoulder under bones without causing friction. *Id.* at 14. Inflammation of the bursa can cause bursitis, which causes pain with movement. *Id.* Dr. Ramundo opined that petitioner also developed adhesive capsulitis (also known as frozen shoulder). *Id.* at 15. He concluded that these conditions were "referring pain up to her neck, and then the neck was going into spasm because of the decreased range of motion of the left shoulder, and that was causing headaches." Tr. 10. Dr. Ramundo opined that petitioner was the first individual he had treated for a shoulder injury related to vaccine administration (SIRVA). Tr. 42-43. He opined that "millions of flu shots are given, and it's a very uncommon finding." *Id.* at 43.

Dr. Ramundo testified that when he first evaluated petitioner, he was not aware that she previously applied for Social Security Disability based on chronic fatigue syndrome and additional symptoms, including headaches. Tr. 44-45. However, he had been aware that Dr. Smith had made the assessment of chronic fatigue syndrome. Tr. 46-47. Dr. Ramundo opined that the flu vaccination caused petitioner's left shoulder pain and limited range of motion (and as described above, sequelae extending to left arm weakness; neck pain; and headaches). He did not opine that the flu vaccination caused or contributed to lower back or lower extremity symptoms. *Id.* at 43, 49-50.

B. Additional Affidavits and Testimony

1. Alla Goldman

At the entitlement hearing, petitioner was questioned about the August 2000 ADL questionnaire (described above) and asked whether her routine differed significantly in the year leading up to the October 23, 2015 flu vaccination. Tr. 81-83. She recalled cooking meals "sometimes", "no more than two" dinners per week. Tr. 83-84. She recalled doing "not extensive house cleaning" but some simple vacuuming and dusting. Tr. 84. Petitioner also

recalled that she was driving to some extent. Tr. 87. Petitioner also stated: "I was not in pain [before the vaccine]." Tr. 87-88.

Petitioner testified that she had previously received vaccinations at medical offices. In that setting, she sat on an exam table and the doctor was level with her. Tr. 57. In contrast, upon receiving the 2015 vaccine at Walgreens, she recalled "sitting on the low bench, fully dressed, with just my left sleeve pulled down a little, and the pharmacist was standing right above me, and I just know that we were not leveled." Tr. 56-57. She recalled that the pharmacist administered the vaccination in her "left upper arm". Tr. 56. She confirmed that she was right-hand dominant. Tr. 97.

Petitioner testified that upon receiving the vaccination, it hurt initially "as… usual". Tr. 58. But then, as the day went on, she continued to have pain which was severe. *Id.*

I asked whether petitioner remembered the time of day that she received the vaccination. Tr. 58. She believed that it was in the afternoon. *Id.* Petitioner stated that she had pain at dinnertime. Tr. 59. She rated this pain as eleven on a scale from zero out of ten. Tr. 59-60.

Petitioner recalled having difficulty sleeping on her left side "almost immediately". Pet. Ex. 15 at ¶ 4; Tr. 60, 92. She also recalled having difficulty getting dressed, especially putting her arm into sleeves, beginning the first morning after the vaccination. Pet. Ex. 15 at ¶ 4; Tr. 60, 92. She also recalled having difficulty reaching things overhead and fastening her seat belt. Tr. 60. Her husband helped as much as he could, but he was not always around. *Id.*

Petitioner recalled that at first, she took over-the-counter pain medications (e.g., Tylenol, Aleve) and hoped that her pain would go away over time. However, it persisted throughout November and December 2015. Pet. Ex. 15 at ¶¶ 6-7; Tr. 58-61. Her husband wanted her to seek medical attention. Pet. Ex. 15 at ¶ 7; *see also* Tr. 62. However, her primary care provider, Dr. Smith, was away for the holidays and she had an appointment scheduled for January; she decided to hold off until then rather than seeing a different doctor. Pet. Ex. 15 at ¶ 7; *see also* Tr. 61-62, 92-93. On January 12, 2016, petitioner had the scheduled appointment with Dr. Smith, who assessed bursitis and recommended physical therapy. Pet. Ex. 15 at ¶ 8; Tr. 62-63.

Petitioner testified that physical therapy was helpful. Pet. Ex. 15 at ¶ 14; Tr. 63. However, in summer 2016, she continued to have left shoulder pain (which was "not as severe as it was in the beginning", but still present), limited range of motion, and weakness. She had difficulty with simple household tasks and driving a car. Tr. 64-65. At this point, Dr. Smith referred to Dr. Ramundo, who prescribed further physical therapy, chiropractic treatment, alternative medications, and a TENS unit. Tr. 66-69. Petitioner testified that she continues all of these recommendations, which are all helpful, especially the physical therapy and chiropractic treatment, without which her shoulder pain and range of motion get worse. Tr. 66-69, 73-74; *see also* Pet. Ex. 15 at ¶ 14. On cross-examination, petitioner acknowledged that at physical therapy sessions, she "gets something done for [her] back" but stated that "most concentration is… on [her] shoulder". Tr. 93.

Petitioner confirmed that she has not undergone surgery for her left shoulder. Tr. 93. Neither has she received any steroid injections for her left shoulder. Tr. 94. Dr. Ramundo suggested a steroid injection once, but petitioner refused because she is "absolutely terrified of needles, especially knowing that all this started with a simple needle." *Id.* Petitioner also averred that Dr. Ramundo said that any steroid injection would provide only a "temporary" benefit which "would help to some extent, but it would have to be repeated." Tr. 94-95. Petitioner testified that she is also concerned about the side effects of both steroids and meloxicam. Tr. 94-95.

Petitioner testified that on a good day, her left shoulder pain is rated at about two or three out of ten. Tr. 70; *see also* Pet. Ex. 15 at ¶ 13. When she is more active, her pain level increases to five or six out of ten. Tr. 70-72; Pet. Ex. 15 at ¶ 10. Petitioner understands her condition to be permanent. Tr. 73-74.

2. Petitioner's Husband

Petitioner's husband submitted an affidavit dated July 30, 2019. Pet. Ex. 16. He also testified at the hearing. Tr. 97-106. The husband testified that throughout the relevant time, he has worked full-time in sales. Tr. 101-02. He went into the office every day. *Id.* at 102. Because of petitioner's chronic fatigue syndrome diagnosis, he was already "doing most of the shopping" and "the heavy-duty homework". Tr. 103; *see also id.* at 105-06.

He averred: "Following my wife's flu shot on October 23, 2015, she was talking about how uncomfortable and stiff her left shoulder and arm felt." Pet. Ex. 16 at ¶ 2. He testified that when he came home from work that day, petitioner "was complaining of unusual pain and numbness in her arm and shoulder, which was kind of unusual because she had previous flu shots and never had the same feeling." Tr. 98-99. He recalled that this was on a Friday night. Tr. 104.[8]

He averred that petitioner experienced "pain that was progressing daily." Pet. Ex. 16 at ¶ 3. He testified that the initial pain was "unbearable." Tr. 99. She had pain and stiffness "in the initial day or two", "increasing gradually". Tr. 99-100. He noticed that she was having difficulty brushing her hair and holding objects within the first week after the flu vaccination. Tr. 105.

The husband recalled that petitioner continued to have increasing pain and stiffness in her left shoulder throughout November and December 2015. *Id.* at 99-100. The husband testified that during the holidays, they would usually see friends, but that was more difficult because petitioner was in constant pain and did not want to see anyone. *Id.* at 100. Throughout this period, petitioner's pain was increasing day by day, and she was crying as a result, but she waited for her previously scheduled appointment with Dr. Smith in January 2016. *Id.*; *see also* Pet. Ex. 16 at ¶ 7.

[8] *See also* October 2015 calendar, available at https://www.timeanddate.com/calendar/monthly.html?year=2015&month=10&country=1 (reflecting that the date of vaccination, October 23, 2015, was a Friday).

The husband testified that petitioner has good days and bad days. Tr. 101. While he already did most of the shopping and housework, since petitioner sustained this left shoulder injury, he does a greater share and also helps with her activities of daily living, such as getting dressed. *Id.* at 102-03. Petitioner's more or less "constant" pain also affects her mood, which has an impact on their relationship. *Id.* at 103.

3. Petitioner's Daughter

Petitioner's adult daughter also submitted an affidavit dated August 1, 2019. Pet. Ex. 15. She averred: "Following my mother's flu shot on October 23, 2015, she experienced unusual shoulder discomfort and pain." *Id.* at ¶ 2. The daughter also averred, consistent with the other witnesses, that petitioner's symptoms worsened over time but she put off seeking medical attention until her prescheduled appointment with Dr. Smith in January 2016. *Id.* at ¶¶ 3-5. The daughter did not testify at the hearing.

III. Finding of Fact

Prior to determining vaccine causation, there is one factual issue that must be resolved. The question is whether petitioner suffered the onset of left shoulder pain within 48 hours after receipt of the flu vaccination on October 23, 2015.

A. Legal Standard

Petitioner bears the burden of establishing the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). The special master "may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery*, 42 Fed. Cl. at 391. The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional , everything that happened during the

relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

B. Party Contentions

Respondent contends that the medical records do not establish that petitioner suffered the first symptoms or manifestation of onset of a shoulder injury within 48 hours of the October 2015 flu vaccination. Respondent observes a gap in the medical records between the October 23, 2015 flu vaccination and the next medical encounter on January 12, 2016. Respondent argues that the January 12, 2016 encounter does not clearly establish the onset of pain, indicating only "that the pain occurred 'after' the flu vaccine." Resp. Report at 5, citing Pet. Ex. 2 at 75. Respondent also argues that at the initial physical therapy evaluation on March 7, 2016, "petitioner reported that her range of motion in her affected shoulder was not limited until January 2016, over two-and-a-half months after her October 23, 2015, flu vaccination." Resp. Report at 5, citing Pet. Ex. 4 at 91.

After the submission of additional affidavits and testimony at the May 2020 hearing, respondent maintains that petitioner has not established onset within 48 hours. Respondent avers: "[I]t is undisputed that petitioner did not seek medical treatment until January 12, 2016, which is over two months post-vaccination." Resp. Post-Hearing Brief at 2, citing Tr. 61:15-20. "And the only evidence that her pain began within 48 hours after vaccination is petitioner's own testimony, which is insufficient as a matter of law." Resp. Post-Hearing Brief at 2-3, citing 42 U.S.C. § 300aa-13(a)(1).

Petitioner maintains that she has established onset within 48 hours of the flu vaccination. She avers that it is illogical to require production of "medical records from the time of onset or lose as a matter of law." Pet. Post-Hearing Reply at 1. Petitioner avers that especially in a SIRVA case, there are many reasons for not seeking immediate treatment. *Id.* Petitioner avers that she initially thought that her shoulder pain would go away without medical intervention and

it was not life-threatening. *Id.* at 1-2. Petitioner also observes that the Vaccine Act requires that a special master make a determination based on the record as a whole. *Id.* at 2, citing 42 U.S.C. § 300aa-13(a)(1). Moreover, a special master may find that the time period for the first symptom or manifestation of onset required for a Table injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having recorded outside such a period". *Id.*, citing 42 U.S.C. § 300aa-13(b)(2). A determination of onset must instead be based on "a preponderance of the evidence". *Id.*, citing, e.g., *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664v, 2018 WL 3083140 at *5 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) (holding that despite a six-month delay in seeking treatment, the petitioner established onset of shoulder pain within 48 hours), *mot. for rev. denied*, 42 Fed. Cl. 329 (2019). Petitioner argues that similar to the petitioner in *Tenneson*, she did not seek immediate treatment for her shoulder injury, but a preponderance of evidence – including Dr. Ramundo's later medical records and her own testimony – support onset after the flu vaccination. Pet. Post-Hearing Reply at 3. She argues that "there is no cause to dispute immediate onset." *Id.*

C. Discussion and Conclusion

Following a review of the entire record and the parties' briefs, I find that there is preponderant evidence that petitioner experienced the onset of left shoulder pain within 48 hours of the flu vaccination administered on October 23, 2015.

First, the lack of contemporaneous medical records reflecting petitioner's left shoulder injury until January 12, 2016 does not defeat petitioner's claim. There are *no* medical encounters in the intervening period. The available records reflect that petitioner relied on periodic scheduled appointments with her established primary care provider, Dr. Smith, for her longstanding chronic fatigue syndrome and associated symptoms. Petitioner avers consistently throughout her affidavit, testimony, and post-hearing reply brief that she waited until her next scheduled appointment with Dr. Smith on January 12, 2016, to seek treatment for her new shoulder injury. Petitioner also avers that she initially treated the shoulder with over-the-counter pain medications and hoped that it would get better. She did not believe the injury to warrant emergency attention. She additionally described that the shoulder pain and limitations to range of motion were "progressive" leading up to that appointment with Dr. Smith.

Once petitioner did seek medical attention for her left shoulder, the records consistently reflect a temporal association with the flu vaccine. In the first record on January 12, 2016, Dr. Smith recorded simply: "left arm pain after receiving influenza vaccine". Pet. Ex. 2 at 75. While Dr. Smith does not expressly state that this pain began within 48 hours of the vaccine, he does not suggest any longer period of time either. Dr. Smith's record certainly indicates that petitioner dated and attributed the onset of her pain to the receipt of her flu shot, which is consistent with petitioner and her husband's later, more detailed recollections in affidavits and testimony. I am not inclined to construe the record against petitioner merely because Dr. Smith did not specifically note onset beginning within 48 hours, which is a legal and not a medical standard.

Respondent emphasizes that the March 7, 2016, physical therapy initial consult record provides that "petitioner reported that her range of motion in her affected shoulder was not limited until January 2016, over two-and-a-half months after her October 23, 2015, flu vaccination." Resp. Report at 5, citing Pet. Ex. 4 at 91. This is a selective quotation from the record, which in fact states, "Patient's shoulder pain began in OCT 2015, after she received a flu shot in the left shoulder. Her ROM became limited in January 2016..." Pet. Ex. 4 at 91. This physical therapy record is in fact consistent with petitioner's account that her shoulder *pain* began within 48 hours of the vaccination and range of motion became limited later.

Later medical records are consistent with the above. *See, e.g.*, Pet. Ex. 3 at 22-23 (MRI report with the corrected clinical history of "shoulder pain and limited range of motion since the end of October"); Pet. Ex. 3 at 3 at 21-22 (petitioner's new patient intake form for orthopedist Dr. Ahmad, providing that the left shoulder injury occurred "following flu shot on Oct. 23, 2015"); Pet. Ex. 4 at 6 (petitioner's physical therapy patient health questionnaire, providing that she began to have "severe shoulder pain", "following the flu shot of 10/23/15"); Pet. Ex. 5 at 14 (Dr. Ramundo's record, during the June 2016 initial consult, that petitioner's left shoulder pain "began about 8 months ago, after a flu shot").

The later affidavits and testimony do not conflict with these medical records. Rather, they are consistent and provide additional detail. Accordingly, there is preponderant evidence that petitioner experienced the onset of left shoulder pain within 48 hours of the flu vaccination administered on October 23, 2015.

IV. Ruling on Entitlement

A. Legal Standard

The Vaccine Act provides two avenues for petitioners to receive compensation. The petitioner may demonstrate either that she suffered a "Table" injury, or that she suffered a different injury which was caused-in-fact by a vaccine listed on the Vaccine Injury Table. §§ 3000aa-13(a)(1)(A), 11(c)(1); *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). To establish causation in fact, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

B. *Althen* Prong One

Althen prong one requires preponderant evidence of a medical theory that the vaccine at issue can cause the injury alleged. *Althen*, 418 F.3d at 1278. Respondent argues that petitioner bears this burden because she initiated her claim on November 22, 2016, and it is therefore governed by a version of the Vaccine Injury Table which does not list SIRVA as a recognized injury within 48 hours of flu vaccines intended for intramuscular administration, that is, a "Table" injury. Resp. Report at 5, n. 2.

However, the Federal Circuit has held that respondent's recognition of a link between a specific vaccine and a specific injury, through its addition to the Vaccine Injury Table, supports petitioner's burden under *Althen* prong one. *Doe 21 v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds*, *Paterek v. Sec'y of Health & Human Servs.*, 527 Fed. Appx. 875 (Fed. Cir. 2013). Here, respondent acknowledges that he revised the Vaccine Injury Table to create a presumption of causation for SIRVA with onset within 48 hours of flu vaccine intended for intramuscular administration. The revised Table is effective for claims filed on or after March 21, 2017, merely four months after the filing of petitioner's claim. *See* Resp. Report at n. 2, citing 42 C.F.R. §§ 100.3(a)(XIV)(B), (e)(1); 82. Fed. Reg. 11321 (Fed. 22, 2017).[9]

Here, while respondent argues that the revised Table does not govern petitioner's claim, he does not dispute that flu vaccine intended for intramuscular administration can cause SIRVA. Former Chief Special Master Dorsey has noted the "well-established track record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program." *See, e.g.*, *Gentile v. Sec'y of Health & Human Servs.*, No. 16-980V, 2018 WL 6540025 at *8 (Fed. Cl. Oct. 29, 2018) (collecting cases). Based on respondent's consistent recognition that flu vaccines intended for intramuscular administration can cause SIRVA, petitioner's claim which is consistent with numerous claims falling under the revised Table, and the supportive opinion from petitioner's treating physician, I find that there is preponderant evidence for *Althen* prong one.

C. *Althen* Prong Two

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [her] injury." *Althen*, 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen,* 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Human Servs.,* 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148.

Although petitioner's claim was filed four months too early to be governed by the revised Vaccine Injury Table listing SIRVA as a Table injury, the Table's qualifications and aids for interpretation (QAI) for SIRVA are persuasive regarding the factors necessary to demonstrate a logical sequence of cause and effect. *See, e.g.*, *Tenneson*, 2018 WL 3083140 at *7; *Gentile*, 2018 WL 6540025 at *9.

[9] Indeed, if petitioner had filed her claim just a few months later, after the effective date of the addition of SIRVA, it still would have been timely filed. *See* 42 U.S.C. § 300aa-16(a)(2) (providing that a petition for compensation for an injury in association with a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, must be filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset… of such injury"); Amended Petition (alleging that petitioner experienced the onset of left shoulder pain within 48 hours of the flu vaccination administered on October 23, 2015).

The QAI provide that a vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all four criteria, quoted in the following subheadings and applied below to petitioner's specific case. 82 Fed. Reg. 6303, codified at 42 C.F.R. § 100.3(c)(10)(i) – (iv).

1. **"No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings and/or diagnostic studies occurring after vaccine injection". 42 C.F.R. § 100.3(c)(10)(i).**

Respondent avers that petitioner cannot establish this first criteria because she has not filed all necessary records.

Early in this case, petitioner filed medical records beginning in October 2012, three years prior to the vaccination. These records reflect regular care by Dr. Smith for chronic fatigue syndrome, fibromyalgia with trigger points, headaches, dizziness, and insomnia. Pet. Ex. 2. Neither respondent nor I, in my own review, identified any complaints of left shoulder pain, inflammation, or dysfunction in the three years prior to the vaccination on October 16, 2015.

Later in the life of the case, respondent retained his own expert to evaluate petitioner's proposed life care plan. On January 16, 2020, respondent's counsel – apparently on behalf of his life care planner – requested additional records from petitioner including Social Security Disability (SSD) records and Medicare records. Resp. Status Report filed January 21, 2020 (ECF No. 62); Resp. Status Report filed February 24, 2020 (ECF No. 64). Petitioner subsequently filed several categories of records, including the file from her initial determination of eligibility for SSD payments. Petitioner was found to be disabled based on a diagnosis of chronic fatigue syndrome. There are no specific references to the left shoulder. The SSD file contained medical records from approximately 1999 – 2002. *See* Pet. Exs. 23, 25. However, petitioner did not file any further SSD records or any Medicare records. Nor did petitioner acknowledge respondent's requests for those records in a status report filed on March 2, 2020 (ECF No. 67).

On March 17, 2020, I held a lengthy status conference on topics including respondent's requests for records. According to my order memorializing the status conference, respondent did not state that he was seeking any SSD records beyond what had already been filed. Respondent did note his prior requests for Medicare records. Petitioner's counsel had not pursued that request to date. During the call, petitioner's counsel averred that obtaining documentation of what particular healthcare services were rendered to petitioner and covered by Medicare would be difficult and time-consuming. Petitioner's counsel also stated that Medicare's scope of coverage is in the public record and suggested that was more efficient to determining what offsets were required in this case. I encouraged petitioner's counsel and life care planner to locate that information. In addition:

> I also encourage[d] respondent's counsel and life care planner to evaluate whether the information they are seeking from Medicare is indeed necessary. If respondent continues to believe that it is, respondent should file a status report explaining why and I will consider the issue at that time. However, I am currently

> not inclined to delay the hearing in this case while we wait for Medicare billing records without a compelling reason to do so.

Scheduling Order filed March 18, 2020 (ECF No. 71) at 2. Respondent did not raise this issue again before the hearing in May 2020.

In his post-hearing brief, respondent avers that the record is not complete because petitioner was still receiving SSD benefits on the date of vaccination in 2015, and that: "Further, per the finding of disability and award, the decision was to be reviewed every three years and petitioner admitted that she continued to send records of her doctors' visits to the Social Security Administration (SSA)." Resp. Post-Hearing Response at 3, citing Tr. 88-89. "However, the only records that were filed from SSA were from 2000 – 2002." *Id.* Respondent avers that without additional SSA records – from 2002 to 2015? – as well as Medicare records, the record is incomplete. Resp. Post-Hearing Response at 3.

I disagree with respondent's assertion that the record is not sufficiently complete to evaluate petitioner's pre-existing condition. A Vaccine Act petition must be accompanied by all "pre- and post-injury physician or clinic records (including all relevant growth charts and test results." 42 U.S.C. § 300aa(11)(c); *see also* Vaccine Rule 2(c)(2)(A) (providing no additional detail about what *pre-vaccination* records must be filed). The Vaccine Guidelines recommend that in a claim involving a vaccinee who is an adult, "the filed records should include all records from all primary care providers for three years prior to the administration of the vaccine(s) alleged to be causal."[10] Petitioner has filed these records from her primary care provider Dr. Smith. *See* Pet. Ex. 2 at 1 (cover page requesting "all medical, vaccination and billing records in your [Dr. Smith's office's] possession relating to Alla Goldman from 10/1/12 to the present"). Additionally, petitioner has filed multiple records from other medical providers which appear to provide a comprehensive picture of her medical condition.

Respondent is not only seeking the records required by the Vaccine Act, but copies of those records required by the Social Security Administration to evaluate whether petitioner remains eligible for SSD payments for an entirely separate medical condition which is not at issue in this case. As an initial matter, as noted above I had some concern that this request will create additional delay in the resolution of this claim that has already been sufficiently delayed. *See* Vaccine Rule 1(b) (providing that in any matter not specifically addressed by the Vaccine Rules, the special master or the court shall uphold the purpose of the Vaccine Act "to decide the case promptly and efficiently"). More significantly, it is highly likely that any records produced would be entirely duplicative of records already filed. Requesting fifteen years of Medicare billing records appeared to me to be little more than a fishing expedition by respondent's life care planner. Thus, I do not find respondent's requests (for either the SSA's copies of records or Medicare billing statements) likely to yield additional records from either Dr. Smith or other medical providers from prior to the vaccination, nor that they are "reasonable and necessary" to my resolution of whether petitioner had any pre-vaccination history of pain, inflammation or dysfunction of the affected shoulder that would explain the injury alleged here. *See* Vaccine

[10] Guidelines for Practice Under the National Vaccine Injury Compensation Program (as revised April 24, 2020), available at https://www.uscfc.uscourts.gov/vaccine-guidelines.

Rule 7 (providing that there is no discovery as a matter of right and that the special master shall determine the scope of discovery); *See also In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Various Petitioners v. Sec'y of Health & Human Servs.*, 2007 WL 1983780 at *6 (Fed. Cl. Spec. Mstrs. May 25, 2007) (providing that a special master has "broad discretion" in determining what material is necessary or not, in the overall context of the case). Accordingly, petitioner has established the first QAI criteria.

2. "Pain occurs within the specified time period [within 48 hours after vaccination]", 42 C.F.R. §§ 100.3(a), (c)(10)(ii).

As discussed above, I have made a finding of fact that petitioner suffered the onset of left shoulder pain within 48 hours after receipt of the flu vaccination on October 23, 2015. Accordingly, petitioner has established the second QAI criteria.

3. "Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered". 42 C.F.R. § 100.3(c)(10)(iii).

As acknowledged above, petitioner had chronic fatigue and generalized myalgias for at least fifteen years before the October 23, 2015 flu vaccination. But afterwards, she had a new, distinct complaint of left shoulder pain and limited range of motion. *See, e,g.*, Pet. Ex. 2 at 75-76 (January 12, 2016 record by Dr. Smith); Pet. Ex. 4 at 91-92 (March 7, 2016 physical therapy initial consult). This complaint remained static for approximately six months.

Then beginning on June 1, 2016, petitioner added a complaint of headache and neck pain. Pet. Ex. 3 at 19-22; *see also* Pet. Ex. 4 at 6; Pet. Ex. 5 at 14-17. As an initial matter, it must be noted that petitioner's pre-vaccination medical history consistently included headaches and generalized myalgias. However, her treating pain medicine physician Dr. Ramundo explained that the shoulder and neck anatomy are connected, and pain in one area can radiate to the other. Tr. 8-10. Dr. Ramundo opined that petitioner's documented bursitis and adhesive capsulitis "was referring pain up to her neck, [which…] was going into spasm [which…] was causing headaches." Tr. 10.

Respondent argues that Dr. Ramundo's opinion is "pure speculation" because he was not aware of petitioner's prior history. Resp. Post-Hearing Response at 6. Upon review, Dr. Ramundo testified that he was not aware that petitioner had applied for SSD fifteen years before the vaccination, and he was not aware of the prior history of *headaches*. However, he was aware of her prior diagnosis of chronic fatigue syndrome (the basis of her eligibility for SSD payments) and he had reviewed the prior records from Dr. Smith. Tr. 44-47.

It is observed that Dr. Ramundo, certainly when he first established care of petitioner, was first and foremost a treating physician. He has board certifications in pain management as well as reading electrodiagnostic tests and anesthesiology. While he was not originally aware of her SSD payments, he was aware of the underlying diagnoses. He also conducted a reasonably comprehensive evaluation of her presenting complaint of left shoulder pain and limited range of motion, associated with neck pain and headaches. This evaluation included obtaining MRIs of both the left shoulder and the cervical spine, as well as an EMG. Based on all of this data, Dr.

Ramundo's opinion – both in his medical records and his more recent testimony – was that the left shoulder pain explained the other symptoms which were recorded later in the course. I found Dr. Ramundo's testimony, which was based upon his extensive treatment of petitioner and his review of her other medical records, to be credible and persuasive. His explanation that the flu vaccine caused petitioner's left shoulder chronic pain and adhesive capsulitis, which affected the mechanics and her shoulder and neck, giving rise to subsequent pain in the neck was well-reasoned particularly in light of the cervical spine MRI which did not reveal any significant pathology at C7-T1 that would explain a C8 radiculopathy. I find that Dr. Ramundo's explanation is reasonably well-supported and grounded in petitioner's medical history, imaging and treatment. In addition, respondent did not retain a medical expert to rebut Dr. Ramundo.

4. "No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)". 42 C.F.R. §100.3(c)(10)(iv).

Respondent argues that this criteria cannot be met because "there is electrodiagnostic evidence that petitioner suffers a left-sided C8 radiculopathy". Resp. Report at n. 2. In support of this proposition, respondent cites to the record of a September 26, 2016 appointment by orthopedist Dr. Ahmad. Pet. Ex. 3 at 9. Dr. Ahmad apparently did not believe that this apparent C8 radiculopathy fully explained petitioner's symptoms. He recorded an impression of "left shoulder glenohumeral joint arthritis and rotator cuff tendinosis with cervical radiculopathy and mild carpal tunnel syndrome." *Id.*

Dr. Ramundo – who is board-certified in both pain medicine and electrodiagnostic medicine – seems well-qualified to evaluate a possible C8 radiculopathy. He is actually the treating physician who ordered the EMG. Afterwards, he reviewed the EMG report but observed that petitioner's "pain is not in a C8 pattern". Pet. Ex. 5 at 11. Dr. Ramundo also ordered an MRI of the cervical spine, which found "no evidence for disc herniation, central stenosis, or neural foraminal stenosis" at C7-T1. Pet. Ex. 12 at 2.[11] In his narrative report, Dr. Ramundo discounted the EMG findings based on this lack of "any significant pathology noted on MRI at C7-T1". Pet. Ex. 10 at 3. Dr. Ramundo concluded: In my medical opinion, her chronic neck pain, shoulder pain, and headaches are secondary to the flu shot that she received because there is not enough pathology warranted on MRI to cause the type of pain syndrome that she has." *Id.* Respondent has not directly responded to this opinion or retained his own medical expert to opine about whether petitioner's symptoms are explained by a left-sided C8 radiculopathy.[12] Based on the evidence before me, I am persuaded by Dr. Ramundo's assessment of the records and find that petitioner has fulfilled the fourth QAI criteria.

[11] Dr. Ahmad's record does not contain any indication that he reviewed the cervical spine MRI. *See* Pet. Ex. 3 at 9-10.

[12] The 2016 EMG also revealed a mild left median neuropathy as seen in carpal tunnel syndrome (which involves symptoms of numbness and tingling in the hand). *See* Pet. Ex. 3 at 9. Respondent has not asserted and I do not see support – either from petitioner's medical records or my underlying knowledge and experience – that this mild left median neuropathy would explain petitioner's symptoms centered in the left *shoulder*.

5. Conclusion

For the foregoing reasons, petitioner has presented preponderant evidence of a logical sequence of cause and effect satisfying *Althen* prong two.

D. *Althen* Prong Three

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. Here, both parties agree that the relevant timeframe for onset of SIRVA is within 48 hours of vaccination. Resp. Post-Hearing Response at 2; Pet. Post-Hearing Reply at 1. In light of the above finding of fact that petitioner suffered the onset of left shoulder pain within 48 hours after receipt of the flu vaccination on October 23, 2015, petitioner has necessarily satisfied *Althen* prong three.

E. Alternative Cause

Respondent has not asserted, nor do I find, that any evidence in the record supports respondent's burden of establishing an alternative cause for petitioner's left shoulder injury which is unrelated to vaccination.

V. Conclusion

Thus, for all the foregoing reasons, I find that petitioner established by a preponderance of the evidence that she suffered the onset of left shoulder pain within 48 hours after receipt of the October 23, 2015 flu vaccination. Petitioner has also established by a preponderance of the evidence that the flu vaccination was the cause-in-fact of her left shoulder injury. Accordingly, she is entitled to compensation for that injury. A separate damages ruling will be issued.

IT IS SO ORDERED.

s/ Thomas L. Gowen
Thomas L. Gowen
Special Master